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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/619,380

07/14/2003

Ty Whitaker

281-398.01

5428

44331 7590 03/17/2008

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

03/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/619,380	Applicant(s) WHITAKER ET AL.	
	Examiner ROBERT L. NASSER	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-11, 13-18, 20-24, 26-28, 30-33, 35, 36, 38-41 and 43-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6, 11, 13-18, 20-23, 27, 28, 30-31, 36, 38-41, 43-46, 50-57 is/are rejected.
- 7) ☒ Claim(s) 7-10, 24, 26, 32, 33, 35 and 47-49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5 and 27, 28, 30 rejected under 35 U.S.C. 102(b) as being anticipated by Harada et al 5759157 in view of Ogura 6524257 . Harada has a device for measuring blood pressure including an inflatable chamber 10, a sensor 12 coupled to the inflatable chamber to measure information indicative of blood pressure, a control module 26 that receives the signal from the patient, a first analysis module 40 for measuring blood pressure during inflation of the inflatable chamber, a second analysis module 42 for measuring pressure during deflation of the inflatable chamber, where the second module is response to a control signal from the module that indicates that he first measurement was abnormal. Accordingly, blood pressure is measured using at least one of the first and second modules. Harada uses a measurement pressure change rate of 2-3 mmhg/sec. Ogura teaches that it is known to continuously vary the cuff pressure by 5 mmhg/sec to measure blood pressure (see column 7, line 67). Harada appears to use the same inflation and deflation rate. Hence, it would have been obvious to modify Harada to use 5 mmhg/sec as the inflation and deflation rate, as it is merely the use of a well known rate in the art. In addition, it is a mere matter of a simple substitution of one deflation rate for another. Claim 2 is rejected in that deflation can be stepwise (see column 8, line 67). Claim 3 is rejected in that when the control signal is normal, the second module is inhibited and when it is abnormal, the

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second module is activated. Claim 4 is rejected in that the blood pressure includes systolic and diastolic. Claim 5 is rejected in that the device includes a reporting module 38. Claims 27-30 are rejected in that Harada also performs the recited method, noting that the second module only measures pressure if necessary.

Claims 6, 23, 31, 46, and 50-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al in view of Ogura, as applied to claims 1-3, 5, 27-28, and 30 above, further in view Hanna 6450966. Hanna detects whether a user is a neonate by comparing a measurement to a stored value, i.e. stored in a data base and adjusts pressurization to avoid injury to the patient. Hence, it would have been obvious to modify the combination to use such a neonate detection, to avoid injury. Claims 50, 52, 54, and 56 are rejected in that the examiner takes official notice that it is well know to provide a mode switch to activates different modes on a measurement device. Ass applied here, it would have been obvious to provide a mode switch for different sized patients.

Claims 11, 13, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al in view of Ogura, as applied to claims 1-3, 5, 27-28, and 30 above, further in view of Taylor et al 6405076. Taylor et al includes a motion detector and allows blood pressure measurements to continue if the motion is below a threshold (see paragraph 6 in column 9). As such, it would have been obvious to modify Harada to include the noise reduction scheme of Taylor, to increase the accuracy of measurement.

Claims 14-17, 21-22, 39, 40, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al in view of Ogura and Taylor at al 6405076, as applied to claims 11-13 and 36-38 above, further in view of Ueno 4870973. The Harada/Taylor combination stops measurement when motion exceeds a threshold, (see column 9, paragraph 4), but it does not notify the user when motion exceeds a threshold. Ueno displays a warning when artifact is detected and measurement is stopped (see abstract, for example). Hence, it would have been obvious to modify the above combination to use such a warning, to alert the user that too much motion or noise is present. Claims 15-17 are rejected in that the examiner takes official notice that both audible and visual warnings are well known. With respect to claims 21 and 22, the examiner notes that in the context of Harada, if the first measurement is stopped due to artifact, the second measurement would be enabled. Claims 39, 40, 44, and 45 are rejected for the reasons given above.

Claims 18, 20, 41, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harada et al in view of Ogura, Taylor at al 6405076 and Ueno 4870973, as applied to claims 14-17, 21-22, 39, 40, and 44-45 above, further in view of Georgi 4592365. Georgi teaches that when measurement is stopped due to artifact, measurement can be resumed if the artifact level falls below the threshold within a predetermined time. Hence, it would have been obvious to modify the combination above to resume measurement, in order to save time needed to retake a measurement.

Claims 7-10, 24, 26, 32, 33, 35, and 47-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form

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including all of the limitations of the base claim and any intervening claims. Claims 6-10, 24, 26, 32, 33, 35, and 47-49 define over the art of record in that none of the art teaches or suggest choosing the deflation measurement when a neonate is detected.

Applicant's arguments filed 12/13/2007 have been fully considered but they are not persuasive.

Applicant has asserted that the examiner has not taken notice of the deflation rate of Harada. The examiner has acknowledged it above. However, it is the examiner's position that the rate of Harada does not affect the analysis of whether it is obvious to modify Harada to use a different rate.

Applicant has further asserted that Harada teaches a deflation rate faster than 3mmhg, but not for making measurements. The examiner agrees with this statement.

Applicant further asserts that since Harada knew about faster inflation rates and did not use the faster rate, that it is evidence that Harada elected not to use faster rates. The examiner vehemently disagrees with this statement. Harada's faster rate is merely a quick inflate up to a sufficient pressure to begin measurements. Such a step decreases the measurement time. Nothing about this suggests that Harada knew about inflation rates faster than 3 mmhg/sec were suitable for measurements.

However, even if Harada did know about such rates, there is no legal basis to conclude that not using the faster rates makes it non-obvious to do so. Applicant has provided no authority to support such a conclusion. Indeed, according to applicant's

theory, a teaching reference could never predate a base reference in an obviousness combination. This position has no basis in the Patent Laws.

Applicant has further asserted that there is no reason to try faster inflation rates, as Harada knew of fast inflation rates and gave no indication to try to measure using such rates. In response, the examiner first notes that there is no evidence of record that Harada actually knew of such rates, only speculation by applicant. Nothing on the record establishes why Harada did not use the faster rates. Indeed, one could speculate several reasons, such as faster rates weren't necessary, Harada was focusing on other parts of the invention, or Harada was not aware of faster rates for measurement. Second, as noted above, even if Harada knew of faster rates and did not use them, it does not mean it would not have been obvious to do so.

Applicant further notes that there is no likelihood of success of using faster rates because the 2002 American national standard warns that fast pressure changes lead to errors. It is the examiner's position that applicant has grossly misconstrued what is stated 2002 standards. All that is stated is that an inflation rate of 3mmhg led to a reading of a systolic pressure of 147 mmhg, while a measurement at an inflation rate of 10mmhg/sec led to a measurement of 140 mmhg. The actual pressure was 149 mm hg. Nothing in the standards states that using inflation rates between 3 and 10 lead to errors. Indeed, the proposed combination is to use 5 mmhg. Nothing in the standards comments on the accuracy of a deflation or inflation rate of 5 mmhg.

Applicant has also asserted that using a faster inflation rate will not predictably work, as there is nothing in the record to teach that faster inflation works better or even

as well. The examiner does not understand the point of this comment. Ogura clearly teaches using a faster pressure change rate. As such, the two rates are equivalents, in that both are useable to measure pressure. . The Supreme Court noted in the KSR decision that it is obvious to substitution one equivalent for another. Alternatively, it also fits the obvious to try rationale of KSR.

Applicant has further stated that the office action relies on conclusory and unsupported statements of proof of obviousness. Again, the examiner reiterates that the combination is motivated under the explicit language of KSR.

Applicant has also asserted that there would be no expectation of success to using a faster rate or no basis to predict that such an attempt would succeed. It is the examiner's position that applicant is ignoring the fact that the rate is actually taught and/or suggested by the prior art.

At the top of page 15 of the previous response, applicant has stated that Harada and Ogura were trying to solve the same problem as applicant. There is no evidence to support this statement. It appears that maybe something is missing, as it appears that maybe applicant is quoting the examiner. Applicant should clarify what is meant.

Applicant has asserted that since both Harada and Ogura knew of higher inflation rates and did not use them, it would not have been obvious to modify Harada in view of Ogura. It is the examiner's position that there simply is no basis in the law for this position. Applicant has not provided evidence as to why Harada did not discuss using a faster inflation rate. Clearly, then, the reference does not teach away from using faster rates, as it does not state that a faster rate is not desirable or won't work. In addition,

the fact that Harada did not choose to use a faster rate does not mean that, at the time of applicant's invention, it would not have been obvious to do so.

Applicant has asserted that had Harada and Ogura had considered using faster rates, they would have filed for patent coverage. The examiner submits that this point has no relevance to the prosecution the hand. It is possible that they did file for patent protection and were rejected. Whatever the reason is that they did not file for patent protection is not relevant to whether it is obvious to combine the teachings.

The examiner is unclear exactly what applicant is trying to argue with the Kubo reference. An inflation measurement rapidly inflates the cuff to a pressure below diastolic and then either stepwise or continuously increases the pressure during a measurement period to a pressure above systolic, at which point the pressure is dumped. A deflation based measurement rapidly inflates the cuff to a pressure above systolic, and then either stepwise or continuously decreases the pressure until diastolic pressure is detected, at which point the cuff pressure is dumped. As such, it seems quite clear to the examiner that there measurement procedures are inverses of each other. Indeed, Harada teaches using 2-3 mmhg/sec for inflation based measurements (column 5, line 48) and 2-3 mmhg/sec for deflation based measurements (column 6, line 28). Indeed, figure 4 of Harada clearly shows the pressurization cycles of inflation and deflation measurements to be inverses of each other.

Applicant has noted that since neither Harada nor Ogura use the faster rates during inflation, there is no motivation to make the combination. However, it is the examiner's position that since Harada has the same rate for inflation and deflation

measurements, a teaching by Ogura of using a faster deflation rate motivates using a faster inflation rate as well.

Applicant's comments concerning whether Ogura was on constructive notice has been noted, but it is the examiner's position that this issue has been addressed ad infinitum already.

Again, it is the examiner's position that no impermissible hindsight has been used.

With respect to claims 6+ and the rejection based on Hanna, applicant has asserted that Hanna only detects a neonatal cuff, and not actually a neonatal patient and that if the wrong cuff is used, an error would occur. The examiner understands that there is some validity to this argument. However, the examiner notes that this is no different than applicant's disclosure, which either flips a switch or downloads data. If the data were entered incorrectly or the switch flipped in error, it would be the same as Hanna. As such, it is the examiner's position that the sensor that detects a neonatal cuff functions identically to the disclosed sensor of applicant and the combination meets the claim language.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
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